IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

DOUGLAS M. RAY, JR.,	)	
	)	
PLAINTIFF,	)	
	)	
v.	)	**Civil No. 3:10cv136**
	)	
ALLERGAN, INC., *et al.*,	)	
	)	
DEFENDANTS.	)	

MEMORANDUM IN SUPPORT OF RULE 59 MOTION FOR NEW TRIAL

Defendant Allergan, Inc. ("Allergan"), by counsel, states as follows in support of its Rule 59 Motion for New Trial ("Motion"):

I. INTRODUCTION

A new trial is warranted because (1) the verdict is against the clear weight of the evidence, (2) Allergan was substantially prejudiced by errors related to the admission of evidence, the questioning of witnesses, and instructions given to the jury, as well as improper argument by Plaintiff's counsel, and (3) enforcement of the judgment would otherwise result in a miscarriage of justice. The particular grounds for this Motion are set forth in detail below.[1]

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[1] A new trial may be granted "for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). *See Bennett v. R&L Carriers Shared Srvs., LLC*, 744 F. Supp. 2d 494, 529 (E.D. Va. 2010). "[A] trial judge has a duty to set aside a verdict and grant a new trial even though it is supported by substantial evidence, if he is of the opinion that the verdict is against the clear weight of the evidence or is based upon evidence that is false or will result in a miscarriage of justice." *Gill v. Rollins Protective Srvs. Co.*, 773 F.2d 592, 594 (4th Cir. 1985). *See also Cline v. Wal-Mart Stores, Inc.*, 144 F.3d 294, 301 (4th Cir. 1998). Unlike in the context of Rule 50, under Rule 59 the Court must compare "opposing proofs," *Ellis v. Int'l Playtex, Inc.*, 745 F.2d 292, 298 (4th Cir. 1984), and "may weigh the evidence and consider the credibility of the witnesses." *King v. McMillan*, 594 F.3d 301, 314 (4th Cir. 2010). "[T]he crucial inquiry is whether an error occurred in the conduct of the trial that was so grievous as to have rendered the trial unfair.'" *Bristol Steel & Iron Works v. Bethlehem Steel Corp.*, 41 F.3d 182, 186 (4th Cir. 1994).

II. ARGUMENT

A. A New Trial Is Warranted Because, For The Reasons Set Forth In Allergan's Renewed Rule 50 Motion For Judgment As A Matter Of Law, The Verdict Is Against The Clear Weight Of The Evidence.

Allergan firmly believes it is entitled to judgment as a matter of law for the reasons set forth in its Memorandum in Support of Rule 50(b) Renewed Motion for Judgment as a Matter of Law ("Renewed Rule 50 Brief"). If the Court denies Allergan's Rule 50(b) motion, Allergan respectfully submits that a new trial should be granted because, for each of the reasons set forth in its Renewed Rule 50 Brief, the verdict is against the clear weight of the evidence. Accordingly, Allergan incorporates the arguments and authorities set forth Renewed Rule 50 Brief by reference as if set forth herein. Allergan respectfully submits that a new trial is also warranted for the reasons set forth below.

B. Allergan Was Substantially Prejudiced By Plaintiff's Improper Questioning And Argument Concerning The Unilateral Addition Of A Boxed Warning Or Other Bold, Prominent Warning At The Top Of The Label, And The Court's Erroneous Jury Instructions Emphasizing The Same.

A failure to warn claim dependent on the notion that a manufacturer should have unilaterally added a boxed warning or equivalent warning to the top of its label is preempted by the federal Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, and its implementing regulations, which prohibit such action. Here, Plaintiff, through repeated questioning of witnesses about boxed warnings and his counsel's argument to the jury about Allergan's failure to add a "bold," "prominent" warning "right up front in the label," based his case upon the notion that Allergan could, and should have unilaterally added a boxed warning (or its functional equivalent) concerning spread of toxin to the top of the BOTOX® label in early 2007. The prejudice inherent in Plaintiff's attempt to impose liability on Allergan for failing to do something it was prohibited from doing by federal law was compounded by erroneous jury

instructions given by the Court both during the presentation of evidence and following closing argument. As a result, the jury's verdict was undoubtedly based on the mistaken belief that Allergan could have unilaterally added a boxed warning or other bold, prominent warning to the top of its label in early 2007. Accordingly, a new trial should be granted.

1. ***Manufacturers of Prescription Drugs and Biologics are Prohibited by the FDCA from Unilaterally Adding Boxed Warnings or Otherwise Changing the Sequence of Information in Their Labels.***

BOTOX® is a biologic. *See* 42 U.S.C. § 262(i). The distribution and sale of prescription drugs and biologics, including product labeling, is regulated by the Food and Drug Administration ("FDA") under the FDCA. *See Wyeth v. Levine*, 129 S. Ct. 1187, 1195 (2009). Within an FDA-approved label, the FDA regulates the content of the label (*see* 21 C.F.R. § 201.57), the order in which the label must be formatted (*see* 21 C.F.R. § 201.56), and the mechanism by which label changes can be made (*see* 21 C.F.R. § 601.12). Plaintiff's central argument – that Allergan could have unilaterally added a boxed warning or other bold, prominent warning to the top of its label without prior FDA approval – contravenes not only FDA's own policy on boxed warnings, but the regulations themselves.

a. ***A "Boxed Warning" is a Distinct Type of Warning That is Closely Regulated by the FDA .***

Within the FDA's regulatory system, boxed warnings play a special role. In 1979, the FDA created "boxed warnings" specifically for "special problems" of the most serious nature. Thus, it promulgated a regulation stating:

> Special problems, particularly those that may lead to death or serious injury, may be required by the Food and Drug Administration to be placed in a prominently displayed box. If a boxed warning is required, its location shall be specified by the Food and Drug Administration.

21 CFR § 201.80(e); *see* 21 C.F.R. §201.57(c)(1) (for products approved after June 2001). Thus, the FDA has always retained full responsibility for determining when a "boxed "warning" is necessary and where that "boxed warning" should go.

During the comment period preceding creation of the "boxed warning" regulation, the FDA was "asked whether a manufacturer may include a boxed warning without prior FDA approval." 44 Fed. Reg. 37434, 37448 (FDA, Jun. 26, 1979). In the clearest of terms, the FDA said no. "[T]o ensure the significance of boxed warnings in drug labeling, they are permitted in labeling only when specifically required by the FDA." *Id.* The FDA's hard-line stance and restraint in requiring "boxed warnings" is driven by its acknowledgment that "overuse of the box will ultimately lead to reducing its effect." 51 Fed. Reg. 43900, 43902 (FDA, Dec. 5, 1986). Unapproved emphasis "might detract from other language of equal or greater importance, and thus mislead or confuse physicians." 44 Fed. Reg. 37434, 37440 (FDA, June 28, 1979). Thus, the FDA "has emphasized that, to ensure the significance of boxed warnings in drug labeling, they are permitted in labeling only when specifically required by FDA." Lars Noah, *The Imperative to Warn; Disentangling the 'Right to Know' from the 'Need to Know' about Consumer Product Hazards*, 11 Yale J. Reg. 293, 331 (1994).

b. *Under the FDA's Regulatory Regime, Allergan Could Not Have Unilaterally Added a "Boxed Warning" to the Top of the BOTOX® Label Without Prior FDA Approval in Either 2006 or 2007.*

The FDA requires prescription drug manufacturers to provide warnings of clinically significant adverse affects causally associated with approved medications. *See* 21 CFR § 201.57(a)(6)-(11). Typically these warnings are added through the FDA's prior approval process. The limited exception to the FDA pre-approval requirement for drug labeling is known as the "changes being effected" ("CBE") regulation, which is contained in 21 C.F.R. § 314.70(a), (b)(2)(v), (c)(6)(iii) (applicable to "drugs") and 21 C.F.R. § 601.12(f)(2) (applicable to

"biologicals"). Under the CBE regulation, a manufacturer of a drug or biological can make certain limited changes to the FDA-approved labeling based on newly acquired information without prior FDA approval so long as the manufacturer submits a supplemental application to the FDA for review and approval when the labeling change is made.[2]

Because BOTOX® is a biologic, the applicable regulation on label changes and CBEs is 21 CFR § 601.12. As of July 17, 2007 – the date of Plaintiff's injection[3] – this regulation provided, in pertinent part:

> (f) *Labeling changes.*
>
> (1) *Labeling changes requiring supplement submission* -- **FDA approval must be obtained before distribution of the product with the labeling change.** Except as described in paragraphs (f)(2) and (f)(3) of this section, an applicant shall submit a supplement describing a proposed change in the package insert, package label, container label, or, if applicable, a Medication Guide required under part 208 of this chapter, and include the information necessary to support the proposed change. The supplement shall clearly highlight the proposed change in the labeling. **An applicant cannot use paragraph (f)(2) of this section to make any change to the information required in § 201.57(a) of this chapter.** An applicant may report the minor changes to the information specified in paragraph (f)(3)(i)(D) of this section in an annual report. The applicant shall obtain approval from FDA prior to distribution of the product with the labeling change.
>
> (2) *Labeling changes requiring supplement submission -- product with a labeling change that may be distributed before FDA approval.*
>
> (i) An applicant shall submit, at the time such change is made, a supplement for any change in the package insert, package label, or container label to reflect newly acquired information, **except for changes to the package**

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[2] The FDA "carefully reviews" proposed CBE labeling changes, has the authority to reject or modify a proposed change "as the agency deems appropriate," and can "bring an enforcement action if the added information makes the labeling false or misleading." 73 Fed. Reg. 2,848, 2,849 (Jan. 16, 2008). *Id.*

> . . . FDA encourages sponsors to consult with FDA prior to adding safety-related information to the labeling for an approved product even when such change is submitted in a CBE supplement, and sponsors typically do so.

Id.

[3] This provision was the same as of June 30, 2006.

> **insert required in § 201.57(a) of this chapter (which must be made under paragraph (f)(1) of this section)**, to accomplish any of the following:
>
> (A) To add or strengthen a contraindication, warning, precaution, or adverse reaction;
>
> (B) To add or strengthen a statement about abuse, dependence, psychological effect, or overdosage;
>
> (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safety of the use of the product; and
>
> (D) To delete false, misleading, or unsupported indications for use or claims for effectiveness.
>
> (E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the product that FDA specifically requests be submitted under this provision.

21 C.F.R. § 601.12(f) (2007) (emphasis added). Thus, by its terms, at all relevant times § 601.12(f)(2) did not permit changes to be made to the label without FDA approval if they concerned items that are "required in § 201.57(a)."

Section 201.57(a), as referenced in § 601.12(f)(2), is commonly referred to as the "Highlights" regulation. As part of the FDA's efforts to enhance the readability and usability of drug labels, in June 2006 the FDA revised § 201.57 to institute a scheme requiring manufacturers to include a "Highlights" section in the beginning of the label, where key information concerning boxed warnings, recent major labeling changes, contraindications, warnings and precautions containing "the most clinically significant information," and adverse reactions would be displayed. 21 C.F.R. § 201.57(a). *See also* Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products Part II, 71 Fed. Reg. 3922 (Jan. 24, 2006). Section 201.57(a)(4) sets forth the requirements with respect to boxed warnings in the "Highlights" section. Boxed warnings, therefore, are not subject to § 601.12(f)(2)'s CBE

requirements, but rather § 601.12(f)(1)'s prior FDA approval requirement. Quite simply, a boxed warning cannot be added to the top of a label that is subject to § 201.57 without prior FDA approval.

Pursuant to 21 C.F.R. § 201.56(b)(1)(i), the BOTOX® label that was in use in July 2007 was subject to § 201.57. Specifically, § 201.56(b)(1)(i) provides, in pertinent part, that "[p]rescription drug products for which a[n] . . . efficacy supplement was approved by the [FDA] between June 30, 2001 and June 30, 2006" . . . "are subject to the labeling requirements in paragraph (d) of this section and § 201.57."[4] On July 19, 2004, the FDA approved an efficacy supplement for BOTOX® with respect to the treatment of primary axillary hyperhidrosis, making Allergan's BOTOX® label subject to § 201.57's requirements. *See* List of FDA Efficacy Supplement Approvals in 2004, at 18, attached as Exhibit A.

Even if the July 2007 BOTOX® label was not subject to § 201.57, and was instead subject to the pre-2006 regulations, Allergan could not have unilaterally added a boxed warning to the top of its label. *See* 21 C.F.R. § 201.80(e)("Special problems, particularly those that may lead to death or serious injury, **may be required by the Food and Drug Administration** to be placed in a prominently displayed box. ... If a boxed warning is required, **its location will be specified by the Food and Drug Administration**." (emphasis added).)

The FDA's system of regulations simply does not provide a mechanism by which a drug manufacturer can unilaterally add a "boxed warning." Under either 21 C.F.R. § 601.12(f) or 21

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[4] By virtue of § 201.56, Allergan was required to submit a new label, conforming to the new labeling content and format requirements of § 201.56(d) and § 201.57, no later than June 30, 2010. *See* 21 C.F.R. § 201.56(c)(3). By virtue of § 201.56(b), however, the BOTOX® label became subject to the new requirements of § 201.57 on June 30, 2006. Thus, if Allergan wanted to change its label after June 30, 2006, it had to comply with § 201.57. The 2009 BOTOX® label complies with § 201.57.

C.F.R. § 201.80(e), before and after June 30, 2006, Allergan was prohibited from unilaterally adding a boxed warning to the top of its label.

c. ***Allergan Could Not Have Placed a "Black Box" Warning Before Other Information on the BOTOX® Label Without Violating Federal Law.***

The system of regulations for drug labeling in place at the relevant time also mandated the specific sequence in which information contained in the label had to be listed. 21 C.F.R. § 201.56. Specifically, 21 C.F.R. § 201.56(d)(1) provided not only that the top of the label was reserved for "Highlights of Prescribing Information," but also that the label "**must contain the specific information** ... under the following headings and subheadings and **in the following order.**" (Emphasis added). The same is true under the pre-June 30, 2006 regulatory regime. Section 201.56(e), which governs the label of older prescription drug products, also states that the label "must **contain the specific information** required under § 201.80 under the following section headings and **in the following order.**" (Emphasis added.) The first topic, required by federal law to be at the very top of the label, is the description of the drug, followed by clinical pharmacology – not warnings, precautions, or event adverse event information.

Thus, not only was Allergan prohibited from unilaterally placing a boxed warning at the top of its label in 2006 and 2007, it also could not unilaterally place any bold, prominent warning (or any warning at all, for that matter), at the top of BOTOX® label because doing so would have required Allergan to violate the sequence mandated by the FDA.

2. ***A Failure to Warn Claim that Depends on the Manufacturer's Failure to Unilaterally Add a Boxed Warning or Equivalent Warning to the Top of Its Label Is Preempted by the FDCA.***

Pursuant to the Supremacy Clause, article VI, clause 2, of the United States Constitution, state laws that conflict with the exercise of federal power are preempted. *See Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153, 102 S. Ct. 3014, 3022 (1982). Generally, state

laws may conflict with federal laws and be preempted in three ways: (1) expressly; (2) impliedly; or (3) because enforcement of the state law would make it impossible for a private party to comply with federal requirements. *See Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372, 120 S. Ct. 2288 (2000); *Anderson v. Sara Lee Corp.*, 508 F.3d 181, 191 (4th Cir. 2007). Federal regulations, such as those enacted by the FDA, "have no less preemptive effect than federal statutes." *Fidelity Fed. Sav. & Loan Ass'n*, 485 U.S. at 153, 102 S. Ct. at 3022. Preemption extends not just to the regulations themselves, but also to agency actions and determinations. *See Wyeth*, 129 S. Ct. at 1198-99.

Thus, to the extent Plaintiff's failure to warn claim is dependent on Allergan's failure to unilaterally add a boxed warning, or otherwise change the sequence of information in the label to add a more prominent warning to the top, it is preempted by the FDCA and the regulations discussed above because it would be impossible for Allergan to both comply with federal law and fulfill the state law tort duties Plaintiff seeks to impose by way of a jury verdict.[5]

3. ***Plaintiff's Questioning and Argument, Compounded by the Court's Erroneous Instructions to the Jury, Make it Highly Likely that the Verdict was Based on the Jury's Mistaken Belief that Allergan Could Have Unilaterally Added a Box Warning or its Equivalent to the Top of the Label in Early 2007.***

Although Plaintiff did not plead his failure to warn claim as one dependent specifically on Allergan's failure to unilaterally add a boxed warning or its equivalent to the top of the label, his counsel clearly presented and argued the case to the jury that way. The singular focus of

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[5] *Wyeth* does not hold to the contrary. There, in finding that the plaintiff's failure to warn claim was not preempted, the Supreme Court relied specifically on the fact Wyeth could have strengthened its warnings using the CBE regulation and found Wyeth failed to provide "clear evidence" that the FDA would not have allowed Wyeth to add a stronger warning using the CBE procedure. *Wyeth*, 129 S. Ct. at 1196-99. The ruling in *Wyeth* is specifically tied to the CBE regulation, the unique regulatory history of Phenergan, and the nature of the warning that was being argued for by the plaintiff, which was not a boxed warning or a change in the sequence of the information contained in the label. The CBE regulation does not apply to boxed warnings.

Plaintiff's case was that Allergan could, and should have unilaterally added a boxed warning or equivalent "bold," "prominent" warning concerning spread of toxin "right up front in the label" in early 2007.[6] The importance of this argument to Plaintiff's case was acknowledged by his counsel in the following exchange with the Court, which took place after the close of evidence during argument over the content of the Court's jury charge:

> THE COURT: .... Are you planning on using the black box issue?
>
> MR. CHESTER: Yes sir, I think I'm whetted [sic] to that. That's how I tried the case. I put that exhibit up.

(Trial Tr. 1518:6-11.)[7]

Plaintiff's counsel began developing the boxed warning theme, and equating boxed warnings with "prominence," with his questioning of Plaintiff's second trial witness, Dr. Hristova. The following excerpt from that examination is relevant:

> Q: Do you have any drugs that you use that have a black box warning on them?
>
> A: Yes.
>
> Q: What is a black box warning?
>
> A: A black box warning is a warning for the physician that the drug has a severe side effects or can cause death. Severe side effects or death, disability, prolonged hospitalization.

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[6] Plaintiff had to rely on the boxed warning argument for several reasons. First, his prescribing physician, Dr. Hristova, testified that she did not have time to read the entire label. (*See* Trial Tr. 484:21-485:10.) This forced him to argue that the risk at issue should have been prominently featured at the top of the label because otherwise, the warning could not possibly have made a difference in Dr. Hristova's prescribing decision. Second, his claim was tied directly to Allergan's failure to send U.S. physicians a copy of the European Dear Doctor Letter or information as formatted in Allergan's Company Core Data Sheet. However, as discussed on pages 28-29 of Allergan's Renewed Rule 50 Brief, the language of those documents is nearly identical in substance to the language in the July 2007 U.S. label; the only material difference was formatting and "prominence," so that is what Plaintiff was resigned to argue. Finally, other than autoimmune encephalitis, all of the symptoms Plaintiff suffered following his July 2007 injection were included in the July 2007 label; they were just not featured in "big", "bold" "prominent" warning at the top of the label.

[7] Cited excerpts from the trial transcript are attached hereto as Exhibit B.

Q: And in general, when you have a drug that's got a black box warning on it, what does it look like in the context of this label right here?

A: **It's always on the top** and it's **with big black letters** and in a big black box.

Q: And **is there anything like that in terms of a prominent warning** on Plaintiff's Exhibit 54, the package insert that was in effect in 2006?

A: No.

* * *

Q: . . . when I first asked you if spread of toxin was in the label, how long, approximately, did it take you to find it?

A: It took me a long time.

Q: And how long would it have taken you to find it if there had been a black box regarding spread of toxin in 2006.

* * *

A: It's very obvious when you open the box. If you have a black box warning this is the first thing, actually this is the first thing the physician generally looks at.

(*Id.* at 463:21-464:12; 470:12-471:7) (emphasis added). In response to another question from Plaintiff's counsel, Dr. Hristova even hinted to the jury that a boxed warning was added to the BOTOX® label after Plaintiff's injury, even though such evidence had been excluded:

Q: Now, how do those serious adverse events have any relevance to you in terms of your decision to inject Mr. Ray and what happened to Mr. Ray?

A: Well, it's a series of adverse events. This is for the first time I see that wording. **Before I saw the black box that came later** . . . .

(*Id.* at 427:1-6) (emphasis added).

Plaintiff's counsel then called Allergan's Chief Scientist, Dr. Mitchell Brin, as an adverse witness, and questioned him extensively about the feasibility of adding a boxed warning. (*See generally* Trial Tr. beginning at 612:19.) Despite Dr. Brin's insistence that he was not a regulatory expert, the Court instructed him to answer counsel's questions about the feasibility of adding a boxed warning. The follow excerpts from Dr. Brin's testimony are relevant:

Q: Would it have been feasible to add this as a black box warning to the United States label in the first half of 2007?

MS. DARLING: Objection, calls for speculation.

THE COURT: Overruled.

A: Not as a unilateral activity, no.

* * *

Q: So it was feasible to put a black box warning regarding spread of toxin on the United States package insert in the first half of 2007?

A: That's not what I said. The question was is it feasible to go to them and to have a letter or a discussion, that's one thing. Was it feasible for us to put a black box warning on or a boxed warning, as they're called now, I don't know.

* * *

THE COURT: No, based on your view and your position in 2007 would the FDA have allowed you to put a black box warning like the one on page 11 of Exhibit 62 on the package insert for your product?

THE WITNESS: They would not have allowed us to do this as a unilateral activity. In other words we couldn't just go to press and print it. That would not be permitted.

(*Id.* at 616:3-617:15.) Dissatisfied with these answers – which came in response to questions that Dr. Brin was instructed to answer, though outside his expertise – Plaintiff's counsel complained to the Court that Dr. Brin had mislead the jury about the feasibility of unilaterally adding a boxed warning, and the Court and gave Plaintiff's counsel an opportunity to develop the issue further. (*Id.* at 621:7-12.) This resulted in further speculation over whether a boxed warning was feasible in 2007. The Court even permitted Plaintiff's counsel to, in effect, become a witness and testify about what he believed the law allowed:

Q: Are you familiar with the United States Supreme Court case of Wyeth versus Levine?

A: I've heard of it, but I'm not familiar with the details.

Q: Are you aware that the United States Supreme Court held that it was a manufacturer's duty to update the label with new and serious safety information and could do so even without prior FDA approval.

MS. DARLING: Objection, foundation, relevance.

THE COURT: He said he doesn't know about it. He said he doesn't know about what the case is. You can ask him a question without linking it to the case.

BY MR. CHESTER:

Q: **You know that the manufacturer of a drug, especially a lethal neurotoxin, has an obligation to warn doctors about new safety information or old safety information via a black box warning even without FDA prior approval?**

MS. DARLING: Objection, relevance.

THE COURT: Overruled.

(*Id.* at 625:17-626:14) (emphasis added).

During the examination of Dr. Brin, the Court also allowed Plaintiff's counsel to superimpose warnings from Allergan's Company Core Data Sheet ("CCDS") over the 2006 label using the Court's evidence presentation system in order to simulate what a boxed warning might have looked like had it been implemented in early 2007:

Q: Now, putting the FDA issue aside for a moment, it would have been pretty easy to take this spread of toxin warning and make it into a black box warning on your label, right?

MS. DARLING: Objection, asked and answered.

BY MR. CHESTER:

Q: Just from the standpoint of your company?

THE COURT: Overruled.

A: I don't believe so.

* * *

Q: In fact, Vince, would you take that spread of toxin warning and put it on the top of Exhibit 54 as a black box, please.

Dr. Brin, is that pretty much what a black box warning looks like on a package insert?

(*Id.* at 629:17-630:2; 630:20-25.) In performing this bit of theatre, Plaintiff's counsel mistakenly showed the jury the boxed warning from the 2009 BOTOX® label, which the Court had previously excluded pursuant to Allergan's motion *in limine*. (*Id.* at 629:17-638:7.)

Although counsel's relentless questioning of Dr. Brin concerning the legal and logistical feasibility of adding a boxed warning was in itself unfairly prejudicial (particularly considering Dr. Brin testified that he was not a regulatory expert), that prejudice was compounded exponentially by an instruction given by the Court during Dr. Brin's testimony. Specifically, in the middle of Dr. Brin's testimony, the Court instructed the jury as follows:

> Just to clear one thing up, Dr. Brin made a statement about what he thought the company could have done about getting a label changed and said he didn't think that the FDA [sic] could do it without the FDA's approval. I will tell you that that isn't correct and give you some more definition and instruction on that at a later, a fuller instruction at a later time.

(*Id.* at 654:21-655:3.) This instruction is not an accurate statement of the law with respect to boxed warnings and its use constituted a significant error. Moreover, because the Court gave this instruction in the midst of Dr. Brin's testimony, it suggested to the jury that Dr. Brin was not credible; a suggestion that Plaintiff's counsel did not hesitate to emphasize as soon as his questioning of Dr. Brin resumed:

> Q: Dr. Brin, do you agree with me that the manufacturer bears responsibility for making sure the warnings concerning its drug are adequate?
>
> A: I do.
>
> Q: It's not the FDA's primary responsibility it's the manufacturer's, correct?
>
> A: I don't have a yes or no answer on that, I'm sorry. I don't know.
>
> Q: The judge knows the law better than you, true?
>
> A: Correct.
>
> THE COURT: I think he's agreed with that for better or for worse. He said he wasn't an expert in the law.

(*Id.* at 655:10-23.) Thus, only after Dr. Brin had been challenged and directly contradicted by the Court in front of the jury on a purely legal issue did the Court recognize what Dr. Brin had contended from the outset; that he was not a regulatory expert and his testimony on the issue therefore lacked a foundation and was speculative. By that point, however, the damage to his

credibility had been done, and Allergan's case had been severely prejudiced.[8] The Court's erroneous instruction to the jury and its corresponding discrediting of Dr. Brin's testimony in front of the jury constituted clear error that alone warrants a new trial.[9] *See Virginia Ry. Co. v. Armentrout*, 166 F.2d 400, 402-06 (4th Cir. 1948) (new trial granted because district court improperly discredited the defendant's key witness in front of the jury).

But Plaintiff counsel's persistent and improper examination of Allergan's employees on this issue did not end with Dr. Brin. Plaintiff also called Allergan's Vice President for Sales, Donald Pearl, as an adverse witness, and questioned him about boxed warnings as follows:

> Q: What is it?
>
> A: It's a safety warning established by the Food and Drug Administration regarding your product.
>
> Q: Okay. Well, it's not just established by the Food and Drug Administration, is it? It can be instituted by the company or by various other governments, right?
>
> MS. DARLING: Objection, foundation, calls for a legal conclusion.
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> THE COURT: Overruled.

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[8] The prejudice arising from the Court's erroneous instruction concerning Allergan's ability to unilaterally add a boxed warning and the Court's direct challenge to Dr. Brin's testimony was particularly severe considering Dr. Brin was one of Allergan's most important witnesses and the first Allergan witness called to testify at trial. In the courtroom, as in life, it is all too true that you never get a second chance to make a first impression. Dr. Brin's discrediting by the Court naturally caused Allergan's counsel to reassess how Dr. Brin's testimony on issues important to Allergan's defense might be received by the jury, and ultimately caused Allergan to significantly curtail its use of him at trial.

[9] Even if Dr. Brin's testimony on this question of law were incorrect, it was error for the Court to give this instruction as it did. Dr. Brin repeatedly stated he was not a regulatory expert and was reluctant to answer the question, but the Court instructed him to do so. Having answered to the best of his ability, it was patently unfair and prejudicial for the Court to discredit his testimony in the manner that it did. The fact the Court gave the instruction that it did is proof that the question itself was not proper for this witness. Thus, Allergan's contemporaneous objection should have been sustained. Further, Plaintiff was free offer contradictory evidence and, if necessary, the Court could have instructed the jury at the close of evidence. That would have at least given the Court and the parties a chance to thoughtfully consider and brief the issue.

A: I wasn't aware that a company could initiate it. I always thought it was initiated by the Food and Drug Administration.

Q: Well, you're not in regulatory, you're just in sales, right?

A: That's it.

* * *

Q: Now, in general **a black box warning on your product, you realize that goes right up at the top** in the big black box?

A: Yes.

Q: In general is that good for sales?

MS. DARLING: Objection, relevance, calls for speculation.

THE COURT: Overruled.

A: Well, it's important for our representatives to share that with physicians.

Q: I understand. Is it good for sales?

A: I don't know how to answer the question, Mr. Chester. Is it good for sales? Does it have –

Q: Does it help you with sales, which is your job?

A: It might make it more complex, yes.

(Trial Tr. 859:2-19; 860:5-20.) The clear suggestion from the questioning in this exchange is that Allergan failed to implement a boxed warning because doing so would hurt sales.[10] Because Allergan could not unilaterally take such action, this suggestion was improper and prejudicial.[11]

Plaintiff counsel's emphasis on boxed warnings or their functional equivalent (bold, prominent warnings at the top of the label) in his questioning of witnesses, coupled with the Court's erroneous jury instruction concerning Dr. Brin's testimony, insured that in the absence of additional instruction to the contrary the jury would decide this case with the mistaken belief that

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[10] Plaintiff made explicit this "suggestion" during his closing argument when he cited Mr. Pearl's testimony. (*See* Trial Tr. 1565:24-1566:6.)

[11] Plaintiff's counsel knew that Mr. Pearl was not a regulatory expert, so it should have been no surprise when he asked Mr. Pearl about an issue of regulatory law that Mr. Pearl could not provide an authoritative response. His attack on Mr. Pearl in this regard, like his attack on Dr. Brin for giving the answer that he did on this issue, was unwarranted and prejudicial.

Allergan could have unilaterally added a boxed warning, or some other bold, prominent warning concerning spread of toxin, to the top of its label in early 2007. Rather than attempting to cure the prejudice caused by this error, however, during trial the Court advised the parties that it was going to give the following jury instruction, which served only to emphasize the error:

> You're instructed that a drug manufacturer may change its label to add or strengthen a warning that is intended to increase the safe use of the drug without waiting for approval of the change by the Food and Drug Administration. That is because it is the obligation of the manufacturer to publish an adequate warning and to ensure that its warnings remain adequate as long as the drug is on the market.

(Trial Tr. 750:17-751:1.) Allergan filed a memorandum opposing this instruction, and twice requested that if the Court insisted on using it that it be modified to also state that "Allergan could not have added a black box warning to its label without prior approval from the FDA."[12] [*See* Doc. No. 181 at 8-9.]

After the close of evidence, the Court ruled that Plaintiff's counsel could not argue to the jury that in early 2007 Allergan should have added a boxed warning unless the jury was also instructed that Allergan could not have done so without prior approval from the FDA, which could be sought by Allergan on an expedited basis. (*See* Trial Tr. 1503:17-1523:21.) Rather than face this instruction, Plaintiff's counsel agreed not to argue to the jury that Allergan should have added a boxed warning. (*Id.* at 1523:11-21.) During debate over this issue, Allergan's counsel expressed concern that Plaintiff's counsel would avoid using the words "black box" during his closing argument, but would still argue that Allergan should have added a prominent, bold warning to the top of its label equivalent to a boxed warning. (*Id.* at 1522:13-17.) This is precisely what Plaintiff's counsel did, as illustrated by the follow excerpts from his closing:

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[12] Allergan also requested that the Court give Allergan's Proposed Instruction D-16 on this issue, but that request was denied. (*See* Section III(E)(2), *infra.*)

- "It should have been very **prominently displayed right up front in the label**, where no one could miss it." (*Id.* at 1559:24-1560:1);
- "Well, the United States label is a local label and guess what's in section 6 through 15, spread of toxin warning with a **big, bold heading**, but it wasn't in the United States label." (*Id.* at 1560:12-15);
- "Now, lets talk about the issue of **prominence**. . . . If you've got something serious to warn them about, don't bury it in the fine print on page 3. **Put it right up front in big, bold letters. That's the law and they didn't do it.**" (*Id.* at 1560:18-1561:4);
- "If there's a serious risk, you need to **put it somewhere prominent** and they didn't do that here, by design." (*Id.* at 1561:23:25);
- "We know that billions of dollars are at stake, and we heard the vice president of sales tell us what our common sense already knew and that is having a **prominent warning about serious adverse events and deaths right up at the beginning of your label** where everybody could see it, . . . that's not good for sales."[13] (*Id.* at 1565:24:1566:6.)

(Emphasis added.) Plaintiff counsel's conscious decision to argue his case to the jury in this manner was no surprise because, as previously noted, he readily admitted that he was wedded to issue because that was how he tried the case. (*Id.* at 1518:6-11.) While making these closing arguments, however, Plaintiff's counsel also repeatedly gestured in front of the jury with his hands indicating the shape of a box, thus emphasizing and reminding the jury of testimony he carefully elicited during trial equating "big," "bold," "prominent" warnings at the top of the label with boxed warnings.[14] The prejudice from counsel's argument and hand gestures is undeniable.

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[13] As noted, the testimony referred to in this argument comes from Plaintiff counsel's questioning of Allergan's Vice President of Sales about the feasibility and consequences of adding a boxed warning. (Trial Tr. 859:2-19; 860:5-20.) In making this argument, Plaintiff's counsel might just as well have used the words "black box" – his intent was clear.

[14] With the Court's permission, granted in response to Allergan's motion [*see* Doc. Nos. 211, 212, 219], on May 26, 2011 Allergan's counsel and Plaintiff's counsel viewed the Court security camera footage showing Plaintiff's counsel's closing. Attached as Exhibit C is a timeline of relevant events from that video prepared by Allergan, as well as a copy of the transcript from that day. Allergan respectfully submits that the video clearly shows the referenced hand gestures, and that those gestures can be linked to those portions of the transcript reflecting Plaintiff counsel's argument about adding "big," "bold," "prominent" warnings to the top of the label.

In an effort to cure this prejudice, Allergan again requested that the Court include a supplemental instruction to the jury stating that Allergan could not have unilaterally added a boxed warning. (*See id.* at 1593:1-11.) Again this request was denied. (*Id.* at 1592:11-1595:4.) The Court ultimately instructed the jury as it had advised the parties it would do, telling the jury without qualification that Allergan could change its label without waiting for FDA approval. (*Id.* at 1653:3-10.) Without the clarifying language repeatedly requested by Allergan (which constituted a correct statement of the law), the Court's use of this instruction was plain error.

Plaintiff chose to argue directly and repeatedly to the jury that it should hold Allergan liable for failing to unilaterally add a boxed warning or its equivalent to the top of its label in early 2007. The risk of unfair prejudice associated with this improper argument was compounded significantly by the Court's erroneous instruction during Dr. Brin's testimony and its supplemental jury instruction. Although some of this prejudice might have been cured if the Court had granted Allergan's repeated requests to instruct the jury that a boxed warning could not have been unilaterally added, those requests were denied. As a result, based on the Court's prior instruction the jury was **required** to believe that Allergan could have unilaterally added a boxed warning in early 2007. Thus, there is a high likelihood that the jury's verdict was based on a theory of recovery that is preempted by the FDCA. For this reason, a new trial should be granted. *See Bank of Montreal v. Signet Bank*, 193 F.3d 818, 834 (4th Cir. 1999) ("We cannot say, with fair assurance, after pondering all that happened without stripping the erroneous action from the whole, that the judgment was not substantially swayed by the error, [therefore] it is impossible to conclude that substantial rights were not affected.").

C. **The Court's Admission Of Expert Testimony From Drs. Hristova And Gershwin Concerning General And Specific Causation Violated Rule 702 And *Daubert*.**

Allergan respectfully submits that the Court erred in allowing Drs. Hristova and Gershwin to offer expert testimony at trial concerning general and specific medical causation because such testimony failed to meet the minimum standards of Rule 702 and *Daubert*. Because this testimony was necessary to Plaintiff's case, its admission substantially prejudiced Allergan. In support of this argument, Allergan incorporates by reference the arguments and authorities set forth at pages 2-3 of its Renewed Rule 50 Brief, as well as the motions and supporting memoranda Allergan previously filed seeking to exclude this expert testimony.[15]

Allergan also respectfully submits that the Court's reasoning in denying Allergan's motions to exclude this testimony, reflected in the transcript of the Court's April 13, 2011 conference call,[16] is fatally flawed, and that the Court otherwise failed to perform its gatekeeping duties. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*). Specifically, a careful review of the studies cited by the Court as having been relied upon by Dr. Hristova and Dr. Gershwin in support of their general causation opinions reveals that reliance on those studies does not satisfy Rule 702 and *Daubert* in this context. Moreover, the Fifth Circuit's decision in *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375 (5th Cir. 2010), cited by the Court, strongly supports exclusion of Dr. Hristova and Dr. Gershwin on grounds they failed to provide reliable testimony that BOTOX® could cause autoimmune encephalitis or any autoimmune process in the brain, or even cross the blood-brain barrier and enter the brain.

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[15] Allergan's motion to exclude Dr. Hristova's testimony and supporting memoranda were filed in this matter as Docket Nos. 63, 64, and 111. Allergan's motion to exclude Dr. Gershwin's testimony and supporting memoranda were filed as Docket Nos. 65, 66, and 110.

[16] A copy of the transcript from the April 13, 2011 conference call is attached as Exhibit D,

D. Other Evidentiary Errors Greatly Prejudiced Allergan's Substantial Rights.

1. Admission of the European Dear Doctor Letter and Other Foreign Regulatory Correspondence Was Error.

Plaintiff relied heavily on the fact that Allergan did not send U.S. physicians a letter like the June 2007 "Dear Doctor Letter" ("DDL") it was required to send in Europe concerning spread of toxin. Plaintiff's counsel cited this as the primary basis for punitive damages, (*see* Trial Tr. 902:24-903:14), and during closing argument argued that it was "the most egregious fact in the whole case." (*Id.* at 1557:12-17.) In this regard, the prejudicial impact of the European DDL on Allergan's defense is undeniable.

Allergan moved *in limine* to exclude the DDL and all other evidence and testimony concerning foreign regulatory activities, submissions, and/or decisions. [*See* Doc. Nos. 85, 86, 123.] The Court denied Allergan's motion with respect to the DDL, (Trial Ex. 64), and also admitted a 2005 French regulatory agency letter. (Trial Ex. 47.) Allergan respectfully submits that the Court erred in admitting these documents, substantially prejudicing Allergan's defense.

First, the DDL and other documents were irrelevant to the issues for which they were offered because they do not mention the risk at issue as defined by the Court – spread of toxin to the central nervous system including the brain – nor do they mention autoimmune encephalitis, encephalitis, autoimmune processes, immune processes of the brain, brain injury, or any central nervous system effects. Thus, they could not be used to prove notice, and Allergan's failure to send the DDL in the United States could not have proximately caused Plaintiff's injuries.

Second, even if the documents did address the risks at issue, their probative value was no greater than the underlying adverse event data upon which they were based. As Allergan argued before trial, while underlying adverse event data may be relevant to prove notice of a particular

condition, the foreign regulatory activity based on that data is not. The fact these documents were issued under foreign standards, guidelines, and objectives also limits their probative value.

Plaintiff's counsel devoted significant time to these documents during his opening statement and in his direct examinations of Drs. Hristova and Brin, among others. (*See* Trial Tr. 142:4-15; 424:16-426:12; 596:5-597:12.) He also repeatedly and improperly referred to these documents as evidence of Allergan's negligence, as demonstrated by his reference to Allergan's failure to send the DDL as "the most egregious fact in the whole case," (*id.* at 1557:12-17), and the following excerpt from his closing argument:

> If their spread of toxin warning in their label was so adequate, why did they get a letter from the French government in September 2005 pointing out the serious adverse events and deaths from spread of toxin? . . . . They also got a letter from the Irish government that same year. Finally the entire European Health Authority made them send out a Dear Doctor letter in June of 2005.[17] Why would they do that if their warning was adequate as they claimed?

(*Id.* at 1636:4-14.) Plaintiff counsel's improper suggestion to the jury that it should find Allergan's U.S. label to be inadequate simply because foreign regulatory bodies raised issues concerning Allergan's foreign labeling raises the very concern that is repeatedly cited as a basis for excluding foreign regulatory evidence. *See In re Seroquel Prods. Liab. Litig*, MDL Case No. 6:07-cv-15959-Orl-22DAB, 2009 U.S. Dist. LEXIS 65694, at *270, 276-77 (M.D. Fla. Mar. 11, 2009) (excluding foreign regulatory evidence, citing lack of relevance and overwhelming "likelihood of jury confusion"); *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007) ("allowing admission of evidence of foreign regulatory actions, in a case governed by domestic law, would likely cause jury confusion"); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 531 (W.D. Pa. 2003) (causality assessments submitted to Swiss regulatory authority held

[17] The DDL was actually sent in 2007.

inadmissible on grounds they would be "grossly misleading to a finder of fact").[18] As such, the admission of these documents was prejudicial error and the Court should grant a new trial.

2. ***The Court Erred in Admitting Adverse Event Reports and Compilations of Adverse Event Data.***

Adverse event reports are "merely anecdotal accounts of observations in particular individuals which are not controlled tests, frequently lack analyses and often make little attempt to screen out alternative causes for a patient's condition." *Dellinger v. Pfizer Inc.*, No. 5:03cv95, 2006 U.S. Dist. LEXIS 96355, at *29-30 (W.D.N.C. July 19, 2006) (citing *Cavallo v. Star Enter.*, 892 F. Supp. 756, 765-66 (E.D. Va. 1995). On Allergan's motion,[19] the Court excluded adverse event reports and compilations for purposes of proving causation, but ruled they could be used to prove notice **if** Plaintiff laid a proper foundation at trial showing the reports to be "sufficiently similar" to Plaintiff's injury. (*See* April 13, 2011 Order [Doc. No. 154] at 2.)

At trial, the Court admitted several individual adverse event reports, as well as two compilations of adverse event data – the Coté article (Trial Ex. 46) and Biosoteria report (Trial Ex. 66) – without requiring Plaintiff to demonstrate sufficient similarity to the degree required by relevant precedent.[20] (*See generally, e.g.*, Trial Tr. 431-41). Once those documents were admitted for a limited purpose, Plaintiff's counsel used them generally, and relied upon them

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[18] *See* Doc. No. 86 at 5-8 for additional points and authorities.

[19] Allergan incorporates by reference the arguments set forth in its motion *in limine* and supporting memoranda on this issue, [Doc. Nos. 77, 78, 124,] as well as the relevant portions of its memoranda filed in support of its motion to exclude Dr. Hristova's testimony, [Doc. Nos. 64, 111], its Pre-Verdict Rule 50 Brief, [Doc. No. 190], and its Renewed Rule 50 Brief.

[20] Admission of the Biosoteria report was erroneous for the added reason that it was dated July 16, 2007 – just one day before Plaintiff's injection – and therefore the recommendations made therein could not have put Allergan on notice of anything in time to make a difference in Plaintiff's case. At trial, the Court justified admission of the report on grounds it was based on Allergan's own adverse event data. (*Id.* at 445:1-447:5.) That, however, only justifies admitting the data itself which exists independent of the report; not the conclusions and recommendations contained in the report, which constitute a third party's new analysis of that data.

heavily in attempting to prove causation.[21] For example, through Dr. Hristova, he used the Coté article to suggest BOTOX® could travel to the brain, affect the brain, and cause injury. (*See id.* at 420:17-421:8; 430:7-16 (emphasis added).) He also used the Biosoteria report with Dr. Brin in an attempt to discredit him for his unwillingness to use adverse event data to prove causation:

> Q: . . . did you find in your judgment that BOTOX more likely than not, it's 51 percent, was the cause of any of these serious adverse events?
>
> A: It's not just a yes or no answer. We said that for some of the cases it was possible. We didn't put a weight on it.
>
> Q: Well, possible is less than probable and I'm asking you probable, 51 percent more likely than not do you believe that any one of these 207 serious adverse events were caused by BOTOX based on your review?
>
> A: It's possible.

(*Id.* at 667:18-668:6.) This exchange – one of many during trial concerning adverse events – epitomizes the danger of admitting such data. Even though the Court ruled that adverse event data is not reliable evidence of causation, Plaintiff repeatedly used it for that purpose. This pervasive use of unreliable, anecdotal adverse event data, most of which involved conditions wholly unrelated to Plaintiff's injury, undoubtedly created the mistaken impression within the jury that such data was sufficient to establish a causal link between Plaintiff's injury and BOTOX®. The Court erred in admitting this evidence at all, particularly without requiring Plaintiff to first demonstrate the requisite level of sufficient similarity. Allergan should be granted a new trial at which this evidence is properly excluded.[22]

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[21] He did this even though he represented to the Court that the only two adverse events "in the world" he could offer on causation were the VanDenBoom and Chartier cases, which Plaintiff did not present any evidence of at trial. (FPTC Tr., Vol. I, 67:21-69:11, attached as Exhibit E.)

[22] Plaintiff will likely contend that he only used adverse event data to prove notice or to properly impeach Allergan's witnesses. But this is belied by his closing argument to the jury, where his counsel clearly used the Coté article and Biosoteria report to argue for the existence of a causal link between BOTOX® and Plaintiff's injury. (*See* Trial Tr. 1572:22-1573:10 ("Out of 1,600 [adverse events] in the Coté article. All [Dr. Brin]'ll admit to is possibly one?"); 1573:18-19

3. ***Dr. Joseph's Opinions Concerning CADASIL, Plaintiff's Future Medical Expenses, Life Expectancy, and Related Issues Were Not Disclosed Prior to Trial and Their Admission Substantially Prejudiced Allergan.***

As a treating physician who did not submit a Rule 26 expert report, Dr. Joseph could only testify to knowledge she gained from ordinary treatment of Plaintiff that was documented in her medical records. *See Banks v. Cook*, No. 3:08cv514, 2009 U.S. Dist. LEXIS 5107, at *6 (E.D. Va. Jan. 26, 2009); *McDonald v. Wal-Mart Stores East, LP*, No. 3:07cv425, 2008 U.S. Dist. LEXIS 2599, at *8 n.4 (E.D. Va. Jan. 14, 2008). In this respect, the Court erred in admitting Dr. Joseph's opinions and other testimony concerning (1) the signs, symptoms, and progression of CADASIL (*see* Trial Tr. 1148:16-1149:5); (2) Plaintiff's predisposition to injury from BOTOX® as a result of his preexisting CADASIL (*id.* at 1194:16-1195:2); (3) whether and the extent to which his condition is a result of BOTOX® instead of CADASIL (*id.*); (4) Plaintiff's life expectancy[23] (*id.* at 1149:19-1150:6); and (5) the rate at which he could be expected to incur future medical charges. (*Id.* at 1152:18-1153:2.)

Allergan was severely prejudiced by admission of this testimony because Dr. Joseph's testimony was the only evidence supporting life expectancy and future medical expenses, and the only evidence that even arguably supports the theory that BOTOX® aggravated a pre-existing condition. (*See* Section III(E)(4), *infra.*) Because her opinions were not disclosed in advance, Allergan had no opportunity to submit rebuttal testimony or otherwise prepare for her testimony

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("Five people died, what about them. Oh, well, they determined that was not BOTOX related. Really?"); 1573:20-1574:2 ("What about this one lady, she died 30 days after the BOTOX from aspiration pneumonia which is the number one killing mechanism of BOTOX that's not related. None of those five deaths are related and there's nobody to look over it").)

[23] Dr. Joseph's testimony concerning life expectancy was also improper because it was not stated to any reasonable degree of medical probability. (*See* Trial Tr. 1150:1-6 ("[i]t's impossible to predict" Plaintiff's life expectancy "with any certainty"; two years is only a "best estimate").) *See also McDonald*, 2008 U.S. Dist. LEXIS 2599, at *8 n.4.

in advance of trial. Without her speculative testimony concerning future expenses, Plaintiff's special damages would be reduced by more than $300,000 as demonstrated by this excerpt from Plaintiff's closing argument to the jury:

> He's incurred $640,000 over the last four years. It's just shy of four years. If he lives two years and incurs medical expenses at that same rate, Dr. Joseph said it would be higher in the future because he's so sick now. But assume it was just at the same rate for another two years. That would be half that amount or $320,000 in the future.

(Trial Tr. 1587:21-1588:4.) Because the Court's erroneous admission of these previously undisclosed expert opinions substantially prejudiced Allergan, a new trial is warranted.

4. *The Court Erred in Limiting Allergan's Cross-Examination of Dr. Gershwin.*

During direct examination, Dr. Gershwin testified that he had been an expert witness "[l]ots of times," and that courts "almost always" accepted him as an expert. (*Id.* at 919:6-13.) He further testified about his work in breast implant and latex glove litigation, and implied that his work in the latex glove litigation helped "change the manufacturing process for latex gloves" and nearly eliminate latex glove allergies. (*Id.* at 919:14-920:11.) Thus, the jury likely inferred that Dr. Gershwin's methodologies were sound and generally accepted.

Allergan's counsel sought to cross examine Dr. Gershwin about this experience to demonstrate to the jury that opinions like those he offered in this case had previously been excluded.[24] Despite Plaintiff counsel's consent to this line of questioning, the Court instructed Allergan's counsel to move through it "very quickly," and eventually cut the line of questioning off altogether. (*See id.* at 949:2-954:25.) The Court thus stifled a critical inquiry aimed at rebutting the impression created by Plaintiff's counsel on direct that Dr. Gershwin's theories on autoimmune disorders had been generally accepted. Given the importance of Dr. Gershwin's

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[24] Allergan's offer of proof on this issue is set forth at Trial Tr. 1004:24-1006:4.

testimony to Plaintiff's case and the relationship between his theory in this case to his theories in prior cases, Allergan's inability to adequately explore this issue substantially prejudiced its case.

5. ***The Court Erred in Limiting Direct Testimony of Drs. Brent and Saxon.***

During Allergan's direct examination of Dr. Brent, the Court erroneously precluded Allergan from soliciting testimony rebutting Dr. Hristova's testimony concerning the Wiegand study, in which FDA scientists injected botulinum toxin into the muscles of cats. (*See* Trial Tr. 450:3-455:12.) Dr. Hristova specifically testified (1) that the Wiegand study suggested that 90% of injections of botulinum toxin travelled outside of the injected muscle (*id.* at 450:14-21), and (2) that the ability of botulinum toxin to travel outside of the injected muscle is "very relevant" to whether botulinum toxin could enter the central nervous system. When Allergan sought to question Dr. Brent about the Wiegand Study and the related 2003 Tang-Lui Study, the Court cautioned that doing so would open the door for Plaintiff to address the 2008 Antonucci Study, even though the latter study post-dated Plaintiff's injection. (*See id.* at 1274:24-1275:7.) Allergan was thus left with the Hobson's choice of leaving Dr. Hristova's testimony concerning the Wiegand study unchallenged or opening the door to irrelevant, prejudicial evidence. This limitation on Dr. Brent's testimony concerning key issues related to spread of toxin was unwarranted and unfair, particularly considering such testimony was properly disclosed and was not duplicative of other expert testimony.

The Court also erred in precluding Dr. Saxon from testifying on a host of issues based on statements made by Allergan's counsel during the Final Pretrial Conference. (*See id.* at 1366:12-1369:11 (precluding Dr. Saxon from testifying on any issue related directly to Plaintiff); 1382:25-1384:14 (precluding Dr. Saxon from testifying on IGG index).) The Court's ruling with respect to this issue was based on an incorrect and unfair interpretation of a discussion between

counsel and the Court that took place during the Final Pretrial Conference in the specific context of Plaintiff's Motion to Strike Excessive Causation Experts. During that discussion, Allergan's counsel made representations about the scope of expert testimony in direct response to the Court's request that counsel explain how the testimony of each designated expert would be different. Thus, the purpose of the discussion was to explain the differences in each expert's testimony, not to provide a laundry list of the opinions they would offer, which had already been properly disclosed in their Rule 26 reports.[25] (*See* FPTC Tr., Vol. II, 346:19-21 ("THE COURT: Thank you. It seems to me like she explained pretty well how they are different and how they're going to address different topics.").) The discussion in no way encompassed the entirety of each expert's testimony – it only differentiated one expert from the next. Nevertheless, at trial the Court confined the scope of Dr. Saxon's testimony to the very brief summary provided by Allergan's counsel during this discussion at the Final Pretrial Conference. Thus, Dr. Saxon was precluded from discussing Plaintiff's specific condition or the IGG Index, even though his testimony would not have overlapped with another expert's testimony in any way, and even though Allergan's counsel stated at the Final Pretrial Conference that Dr. Saxon would be addressing specific causation (which, by definition, involves testimony about the specific plaintiff). (*See* FPTC Tr., Vol. II, 340:22-23.)

The Court's limitations on the testimony of Drs. Brent and Saxon severely and unfairly prejudiced Allergan's ability to rebut Plaintiff's evidence. Accordingly, a new trial is warranted. *See Bank of Montreal*, 193 F.3d at 833 (abuse of discretion in failing to allow certain evidence).

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[25] The scope of Dr. Saxon's expected testimony was also set forth in Allergan's Opposition to Plaintiff's Motion to Strike Excessive Causation Experts [Doc. No. 92.]

E. The Court's Jury Instructions Were Inadequate, Misleading, and Otherwise Improper Under Virginia Law and Substantially Prejudiced Allergan.[26]

Jury instructions are adequate when, construed as a whole and in light of the entire record, they adequately inform the jury of the controlling legal principles without misleading or confusing the jury to the prejudice of the objecting party. *See Spell v. McDaniel*, 824 F.2d 1380, 1395 (4th Cir. 1987); *Bank of Montreal*, 193 F.3d at 833 (remanding for new trial based on erroneous jury instruction). A district court commits reversible error in refusing a proffered jury instruction when the instruction is correct, was not substantially covered by the court's charge, and dealt with some point in the trial so important that failure to give the instruction seriously impaired the defendant's ability to conduct his defense. *See Worldwide Network Srvcs., LLC v. Dyncorp Int'l, LLC*, 365 F. App'x 432, 439 (4th Cir. 2010). "The evidence relied upon to support an instruction must be 'more than a scintilla.'" *French v. Wal-Mart Stores, Inc.*, No. 98-2135, 1999 U.S. App. LEXIS 20054, at *12 (4th Cir. Aug. 23, 1999) (quoting *Rosen v. Greifenberger*, 257 Va. 373, 513 S.E.2d 861, 865 (Va. 1999)). *See also Francis v. Ingles*, 1 F. App'x 152, 156 (4th Cir. 2001) (proper foundation of expert testimony not established).

1. *The Court's Failure To Warn Instructions (Nos. 17, 20, 22 and 25) Were Erroneous, Incomplete, and Prejudicial.*

The Court's use of Jury Instructions 17, 20, 22, and 25 and its rejection of Allergan's alternative Instructions D-14 and D-15 resulted in erroneous instruction to the jury on the nature and scope of a manufacturer's duty to warn in a prescription drug case and substantial prejudice to Allergan's case.[27]

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[26] A copy of the Court's instructions discussed in this section is attached as Exhibit G.

[27] Allergan filed several trial briefs both in support of its rejected warnings instructions and its objections to the submitted warnings instructions, and hereby incorporates by reference the arguments and controlling authorities therein. [*See* Doc. Nos. 167, 168, 169, 171, 181.]

a. *The instructions failed to tie Allergan's duty to warn to Plaintiff's alleged injury.*

Instructions 17 and 20 provide an inaccurate and incomplete statement of the elements of Plaintiff's failure to warn claim. As demonstrated in Allergan's trial brief, in a prescription drug failure to warn case the relevant inquiry is whether the manufacturer adequately warned the prescriber **of the injury Plaintiff allegedly sustained from taking the drug**. [*See* Doc. No. 171 at 4-7.] There must be a tight "fit" between the required warning and the alleged injury. [*Id.*] Here, the jury was instructed that Allergan had a duty to warn about "dangers of the spread of toxin into the central nervous system, including the brain." Because "dangers" was unqualified and "spread of toxin" was not limited to the brain, the jury was effectively instructed that Allergan's duty to warn extended to **any** dangers of **any** kind relating to spread of toxin into **any** part of the central nervous system, regardless of the rarity of the danger, its clinical significance, or its association with BOTOX®. The injury alleged by Plaintiff, advocated by his counsel throughout trial, and testified to by his retained experts was BOTOX®-triggered autoimmune encephalitis – a progressive immunological brain disease in which the immune system generates antibodies causing inflammation and debilitating destruction of brain cells. There was no "fit," much less a tight "fit," between the warning required by Instructions 17 and 20 and the actual injury alleged.[28] Indeed, the only description of the injury Plaintiff allegedly sustained from BOTOX® is in Part Four of Instruction 20, which states that Plaintiff must prove that BOTOX® proximately caused his "brain injuries." This portion of the instruction, however, did not inform the jury that Allergan's duty to warn was limited to such "brain injuries." Thus, Plaintiff's

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[28] Even Plaintiff's counsel acknowledged that BOTOX®'s ability to cause an immune disorder was proper with respect to a failure to warn instruction. (*See* Pl.'s Mem. Duty to Warn [Doc. No. 160] (suggesting "immunological reactions" as a risk to be included in instruction).)

counsel was free to improperly argue that Allergan was liable for merely failing to warn that BOTOX® "can enter the central nervous system." (Trial Tr. 1552:4-5.) This is significant considering Plaintiff's expert testimony utterly failed to show that BOTOX® could spread to the brain, or that if it did, how it could trigger an autoimmune reaction.

Instructions 17 and 20 also allowed Plaintiff's counsel to argue that Allergan's decision not to send U.S. physicians the European DDL not only constituted a breach of Allergan's duty to warn (*see id.* at1569:14-19), but was **"the most egregious fact in the whole case."** (*Id* at 1557:12-17 (emphasis added).) They also allowed Plaintiff's counsel to improperly argue that adverse events that were unrelated to Plaintiff's alleged injury – such as those contained in the Coté article (*see* Tr. Ex. 46, Trial Tr. 1572:1-14,) and those in the Company Core Data Sheet that were "possibly related to the spread of toxin" (*see* Tr. Ex. 62; Trial Tr. 1553:19-1554:3; 1559:21-1560:17) – triggered Allergan's duty to warn. In short, Instructions 17 and 20 enabled Plaintiff's counsel to argue to the jury that Allergan had a broad duty to incorporate language from various documents into its warning label regardless of the document's purpose and even though the documents did not warn of Plaintiff's actual injury, or any clinically significant injury proven to be causally associated with BOTOX®.

Jury Instruction 22 reinforced the error of Instructions 17 and 20 by instructing that it was sufficient to hold Allergan liable for negligent failure to warn of **any** danger associated with the spread of toxin if "a reasonably prudent person would have anticipated or foreseen that **some injury** might probably result from the negligent act." (Emphasis added). Finally, Jury Instruction 25 supported the improper theme of Instructions 17, 20, and 22 by instructing the jury to "consider whether Allergan's warning label gave a reasonable physician a reasonable indication of the nature and extent of **the potential dangers** in using the drug." (Emphasis

added). Again, the unqualified language referring to "some injury" and "potential dangers" left Plaintiff's burden of proof decoupled from either clinical significance of injury or a "fit" with the injury that Plaintiff allegedly sustained.

Allergan's proffered Instructions D-14 and D-15 would have mitigated these erroneous and prejudicial instructions, but they were rejected.[29] Those instructions properly tied Allergan's duty to warn to Plaintiff's alleged injury – "autoimmune encephalitis." Even if the term "autoimmune encephalitis" was too restrictive, that did not justify the wholesale abandonment of this legal requirement effectuated by Instructions 17, 20, 22, and 25.

b. ***The Court's rejection of Allergan's Instruction D-15 left the jury uninformed of significant limitations on Allergan's duty to warn.***

The Court also erred in rejecting the following language in Allergan's Instruction D-15:

> The manufacturer of a prescription drug has the duty to provide adequate warnings to the prescribing physician about risks causally associated with the drug. . . . The manufacturer does not have a duty to warn about every side effect or hazard that is reported following use of the drug. Further, the manufacturer has no duty to warn about the possibility of rare idiosyncratic reactions to the drug. . . .

This language accurately captures FDA regulations and case law reflecting the sound policy of balancing the prescriber's need to know of clinically significant, causally associated risks against the danger of overloading the prescriber with rare warnings and questionable risks.[30]

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[29] Allergan's Proposed Jury Instructions and Jury Verdict Form were filed as Docket No. 142.

[30] *See* 21 CFR § 201.57(c)(6) ("The labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established"). *See also* [Doc. No. 168 at 2-6]; [Doc. No. 171 at 8-11]. As the Fourth Circuit explained in *Doe v. Miles Labs. Inc.*, "If pharmaceutical companies were required to warn of every suspected risk that could *possibly* attend the use of a drug, the consuming public would be so barraged with warnings that it would undermine the effectiveness of these warnings." 927 F.2d 187, 194-95 (4th Cir. 1991). *See also Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 869 (7th Cir. 2010) (Posner, J., interpreting Virginia law) (explaining that requiring manufacturers to warn of rare conditions would result in "information overload" that "would make the label warnings worthless").

The need for the proffered language of D-15 was particularly acute in this case, considering Plaintiff purports to be the first reported case in the world of BOTOX®-triggered autoimmune encephalitis. The undisputed evidence showed that there has never been a reported adverse event, case study, peer-reviewed article, or any piece of published literature anywhere in the world even hypothesizing that BOTOX® could trigger an immunological, debilitative brain disease.[31] Thus, the omission of the language in D-15 allowed the jury to find Allergan liable for failing to warn of some unrelated perceived general "danger" even if they also concluded that Plaintiff's disease was extremely rare (even unique) or that, at the time of Plaintiff's injection, there was no evidence of any causal association between his condition and BOTOX®.[32]

c. *Instruction 25 failed to adequately instruct the jury on FDA-imposed limitations on the form and content of the BOTOX® warning label.*

Over Allergan's objection, the Court submitted Instruction 25 to the jury while omitting related Instruction 24 pursuant to Plaintiff's objection. The language of Instruction 24 was essentially the same as that included in Allergan's proffered, but rejected, Instruction D-15. Instruction 25 advised the jury to consider in determining the adequacy of the warning:

> [W]hether the warning could be expected to catch the attention of a reasonable prescribing physician, whether it could be understood by a reasonable prescribing physician, and whether it gave to a reasonable physician a reasonable indication of the nature and extent of the potential dangers in using the drug or medicine.

Omitted Instruction 24 clarified, pursuant to Virginia law, that:

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[31] Indeed, Dr. Brent's unrefuted testimony established that there was "no evidence," from any studies or published literature "that BOTOX can cause autoimmune encephalitis" or "any kind of inflammatory brain disease." (Trial Tr. 1257:9-23.)

[32] That the jury found BOTOX® caused Plaintiff's injuries does not indicate that had they been adequately instructed they would have found that Allergan knew or had reason to know in July 2007 that BOTOX® could cause Plaintiff's injuries. Further, as discussed *infra*, the Court's erroneous instructions on causation did not require the jury to consider the critical issue of general causation and left the jury improperly instructed on specific causation.

> An adequate warning need not be perfect; it need only be reasonable. You should consider whether the warning was reasonable, not whether it was the best possible warning.

Use of Instruction 25 without Instruction 24 allowed Plaintiff's counsel to improperly argue in closing that the relevant warnings in the BOTOX® label were buried "in the fine print on page 3," while the law required Allergan to "put it right up front in bold print." (Trial Tr. 1560:18-1561:25.) To the contrary, the applicable FDA regulations governing black box warnings and formatting and sequencing of labeling information prohibit the placement of the relevant warning language "right up front in big bold letters."[33] The substantial prejudice to Allergan of this improper argument is manifest. Moreover, in the absence of expert medical testimony on whether a reasonable prescribing physician would have found the label adequate, Instruction 25 required the jury to engage in impermissible and prejudicial speculation.[34]

2. ***Instruction 26 Erroneously Suggested that Allergan Could Have Unilaterally Changed its Label Without Any Limitations, and Presented a One-Sided View of FDA Approval that Substantially Prejudiced Allergan.***

As noted in Section III(B), *supra*, over Allergan's objection the Court, *sua sponte*, submitted Instruction 26 to the jury, which provided:

> You are instructed that a drug manufacturer may change its label to add or strengthen a warning without waiting for approval of the change by the Food and Drug Administration. That is because it is the obligation of the manufacturer to publish an adequate warning and to ensure that its warnings remain adequate as long as the drug is on the market.

The Court included Instruction 26 despite Plaintiff's agreement to withdraw virtually the same instruction, P-17, in return for Allergan's withdrawal of its Instruction D-16, which stated:

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[33] *See* section III(B)(1), *supra*.

[34] For further discussion of this issue, *see* Renewed Rule 50 Brief at 13-17, and Allergan's Pre-Verdict Rule 50 Brief [Doc. No. 190] at 26-27.

> Before a prescription drug can be sold, the drug must be approved by the U.S. Food and Drug Administration, or "FDA", as safe and effective. The drug's labeling must also be approved by the FDA before the drug can be sold. In approving a drug and its labeling for sale, the FDA takes into consideration the drug's risks, including potentially unknown risks, and balances those risks against the benefits provided by the drug.
>
> The FDA approved BOTOX and the product labeling that was in use in July 2007 at the time of Mr. Ray's injections. You may consider the FDA's approval as evidence that the warnings given by Allergan in July 2007 regarding BOTOX were adequate, that its package inserts provided adequate warnings to prescribing doctors under the circumstances, and that the company exercised ordinary care; although you are not required to do so.

Including Instruction 26 while omitting D-16 informed the jury that Allergan could have strengthened the BOTOX® warning label without waiting for FDA approval, but left the jury uninformed that the FDA had considered the drug's safety in approving the BOTOX® warning label in effect in 2007, and that this approval was evidence that the warning was adequate.

Omitting D-16 also facilitated Plaintiff's counsel's improper argument that BOTOX® clinical trial safety data submitted for FDA approval was ignored:

> Yeah, they submit that to the FDA. The FDA gets millions of pieces of paper every day. They can't go through all that. And he sits up there and says there's no – nothing from the clinical trials show that BOTOX® ever hurt anybody.

(Trial Tr. 1574:3-7.) Failure to include D-16 also left Plaintiff's counsel free to improperly invoke an FDA telephone communication to Allergan in November 2007 raising purported concerns over adverse event reports associated with "spread of toxin." (*See id.* at 1536:15-17.) He rhetorically asked the jury: "Why would [FDA] ... do that if ... [the BOTOX® warning] was so adequate?" (*Id.*) Instruction D-16 would have prevented this one-sided argument.[35]

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[35] Plaintiff's counsel argued at length before the jury about the supposed motives and behavior of officials at the FDA, despite informing the Court the day before that both sides had agreed not to present expert testimony on FDA regulatory issues. (*See* Trial Tr. 1490:13-15.)

Finally, as discussed in Section III(B), *supra*, the use of Instruction 26 without qualification facilitated Plaintiff's counsel's erroneous, improper, and highly prejudicial argument that Allergan should have unilaterally added a warning "right up front, in big, bold letters." (*See id.* at 1560:18-1561:4.)

3. ***The Court Erred in Rejecting Allergan's Proferred Jury Instructions on General Causation.***

The Court erroneously rejected Allergan's proffered Instructions D-14, D-15, D-17, and D-18 and its Proposed Special Jury Verdict Form, all of which would have properly instructed the jury that in order to hold Allergan liable, they must find from the evidence that BOTOX® (1) can cause the injury Plaintiff claims to have sustained and (2) did in fact cause his particular injury.[36] None of the Court's instructions, including its generic form instruction on proximate cause (Instruction 20), addressed these significant evidentiary requirements. Thus, the jury was not required to determine whether Plaintiff proved that as a matter of medical science BOTOX® could cause the injury Plaintiff allegedly suffered – autoimmune encephalitis – before determining whether Plaintiff has this particular injury and whether BOTOX® caused it.

The demands on this jury were great; Plaintiff and his family were most sympathetic, he unquestionably suffers from a debilitating condition, and the medical and scientific evidence presented in this lengthy trial was complex and technical. Under these circumstances, where the likelihood of a verdict motivated by confusion and sympathy was high, detailed, case-specific instructions on the critical legal concepts of general and specific causation and a detailed verdict form were imperative. The Court's refusal to include Allergan's case-specific instructions and

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[36] *See* Allergan's Renewed Rule 50 Brief at 2-13.

special verdict form detailing the requirements of general and specific causation prejudicially affected deliberations and decreased the likelihood of a fair and informed verdict.

4. *Instructions Relating to Multiple Proximate Causes and Aggravation of Preexisting Conditions Were Not Supported by the Evidence.*

Instructions 28 and 33 were not supported by admissible evidence and required the jury to speculate. Plaintiff's theory, as advocated by his counsel throughout trial and testified to by his experts, Drs. Hristova and Gershwin, was that his injuries were solely the result of BOTOX®. Dr. Joseph was the only witness whose testimony arguably provided support for these instructions.[37] (*See id.* at 1194:16-1195:2.) As a treating neurologist with scant experience regarding BOTOX®, CADASIL, or immunological diseases, however, she was not qualified to testify concerning the interrelation of these factors in causing or contributing to Plaintiff's injury.[38] Her speculative testimony cannot support use of these instructions.

5. *The Jury Instruction on Punitive Damages was not Supported by the Evidence.*

For the reasons set forth in Allergan's Renewed Rule 50 Brief at pages 25-29, Instruction 34 on punitive damages should not have been included in the jury charge because (1) the evidence did not support punitive damages and (2) the instruction was prejudicially incomplete. Allergan's proffered, but rejected, Instructions D-24 and D-27 would have cured this prejudice. D-24 correctly states[39] in pertinent part that the jury could not award punitive damages if it found "Allergan showed some degree of care." This instruction squarely fits the evidence in this case; yet the jury was left uninformed on this significant condition concerning punitive damages.

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[37] Plaintiff's counsel acknowledged that Dr. Joseph's testimony was the only support in the record for an aggravation instruction. (*See* Trial Tr. 1460:22-25.)

[38] *See* Allergan's Renewed Rule 50 Brief at 12.

[39] *See, e.g.,* Allergan's Pre-Verdict Rule 50 Brief at 28 (citing *Dudley v. Bungee Int'l Mfg. Corp.*, No. 95-1204, 1996 U.S. App. LEXIS 1267, at *9-10 (4th Cir. Jan. 31, 1996)).

D-27, taken directly from the Supreme Court's decision in *Phillip Morris USA v. Williams*, 549 U.S. 346, 356-57, 127 S. Ct. 1057, 1065 (2007), would have instructed the jury not to award punitive damages for harm caused to others. The Court's refusal to include this instruction allowed Plaintiff's counsel to blatantly and improperly encourage the jury as follows:

> Well, just think of all the Douglas Rays in the United States that were being injected with BOTOX® in 2007 for mild and moderate nonlife-threatening conditions, and Allergan knew about this and they knew they were sitting on this information about risk and they deliberately decided not to warn. That's willful and wanton.

(Trial Tr. 1567:23-1568:4.) This argument was highly prejudicial and undoubtedly contributed to the excessive punitive damages award.

F. Allergan Was Unfairly Prejudiced By The Improper Comments And Arguments Of Plaintiff's Counsel.

A court may set aside a damages award if it is "so excessive as to create the impression that the jury has been influenced by passion or prejudice or has in some way misconceived or misunderstood the facts or the law.'" *King v. McMillan*, 594 F.3d 301, 313 (4th Cir. 2010). In such a case "the court **must** grant a new trial on *both* liability and damages," because "if there is reason to conclude the jury's calculation of damages was substantially affected by emotion, there is also reason to question the jury's underlying assignment of liability." *Allred v. Maersk Line, Ltd.*, 826 F. Supp. 965, 970 (E.D. Va. 1993) (bold emphasis added). *See also Ford Motor Co. v. Bartholomew*, 224 Va. 421, 434 (1982) ("[W]hen the evidence does not preponderate in favor of either party and the damage award is so large that it appears to be solely the product of sympathy, the jury's finding on liability is impeached and the court should order a new trial on all issues."). In the present case, Plaintiff's counsel made several improper arguments to the jury during closing that inherently prejudiced Allergan and warrant a new trial.

First, Plaintiff's counsel asked the jurors to place themselves in Plaintiff's shoes in considering whether $12 million was an appropriate compensatory damages award:

> I'll give you $12 million, you can forget the rest of your life. You're just going to be in bed with brain damage. Do you think he would have made that trade? Do you think any reasonable person would? I don't.

(Trial Tr. 1588:19-23.) "Golden Rule" arguments like this are improper and merit a new trial. *See Leathers v. General Motors Corp.*, 546 F.2d 1083, 1085 (4th Cir. 1976) (granting new trial where plaintiff's counsel asked jury, "how much dollars would it be worth to you, $30 a day, $20, $300 a month?"); *Virginia Ry. Co.*, 166 F.2d at 406 (improper to ask jury to consider what their own humiliation and sense of mental suffering would be if they had to experience what plaintiff experienced); *Moody v. Ford Motor Co.*, 506 F. Supp. 2d 823 (N.D. Okla. 2007) (ordering a new trial based in part on counsel's use of "Golden Rule" argument).

Plaintiff's counsel also improperly asked the jury to consider other large verdicts in deciding damages: "If you think about the highest personal injury verdict you've ever heard of from any trial anywhere, I guarantee you that person wasn't hurt any worse than Douglas Ray has been hurt by this BOTOX." (Trial Tr. 1585:24-1586:3). As noted, he also improperly suggested that in awarding punitive damages, the jury should consider harm caused to other persons who used BOTOX®, violating *Philip Morris USA v. Williams*: "[J]ust think of all the Douglas Rays in the United States that were being injected with BOTOX in 2007 for mild and moderate nonlife-threatening conditions . . . ."[40] (Trial Tr. 1567:23-1568:2.)

Finally, counsel's discussion of Plaintiff's experience in Vietnam during the last moments of closing constituted a blatant and improper appeal to juror sympathy:

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[40] The prejudicial effect of this statement was undoubtedly magnified by counsel's improper commentary about the importance of the case, and his statement to the jury that "others" besides Plaintiff and his family were counting on them. (*Id.* at 1550:15-17; 1639:1-16.)

> A Vietnam veteran who served his country in a thankless war. It wasn't like it is now back then. Vietnam, many of you are old enough to remember this, it was thankless. He saw horrors over there that we can only imagine and the only souvenir he brought home from the Vietnam was this tremor.

(Trial Tr. 1637:14-20.) *See Klotz v. Sears, Roebuck & Co.*, 267 F.2d 53, 54-55 (7th Cir. 1959) (granting new trial due to plaintiff counsel's appeals to juror sympathy).

These statements from Plaintiff's closing argument are alone sufficient to warrant a new trial. Their nature, combined with (1) the extraordinary size of the jury's compensatory and punitive damages verdict (particularly in light of the thin nature of Plaintiff's evidence), (2) the fact that the jury returned a compensatory damage award for the exact amount requested by Plaintiff in closing, and (3) the fact the jury awarded full prejudgment interest dating to July 2007, strongly indicate that the jury's decision was based on passion and prejudice rather than the evidence. Accordingly, a new trial is warranted. *See also Christopher v. State of Florida*, 449 F.3d 1360, 1368 (11th Cir. 2006) (new trial granted on grounds the excessiveness of the verdict cast doubt on the validity of the entire verdict); *Hillard v. Hargraves*, 197 F.R.D. 358, 360 (N.D. Ill. 2000) (granting new trial and holding that trial errors individually, and cumulatively, prejudiced the verdict); *Falkowski v. Johnson*, 148 F.R.D. 132, 135 (D. Del. 1993) (granting new trial based on introduction of extraneous matters by plaintiff's counsel during closing arguments that were reasonably probable to prejudice the jury).

IV. CONCLUSION

The total impact of all irregularities at trial, not each one in isolation, determines whether a new trial is warranted. *See, e.g., United States v. Williams*, 81 F.3d 1434, 1443-44 (7th Cir. 1996); *Llaguno v. Mingey*, 763 F.2d 1560 (7th Cir. 1985). Here, the totality of events set forth above and the fundamental deficiencies in Plaintiff's evidence necessitate a new trial, particularly in light of the jury's excessive verdict.

Respectfully submitted,

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Certificate of Service

I hereby certify that on the 27th day of May, 2011, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will then send notification of such filing to the following:

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